

## **REMARKS**

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:<sup>1</sup>

- I. Claims 1 – 4 are rejected under 35 USC § 112 ¶ 2 as allegedly being indefinite.
- II. Rejections Under 35 USC § 102
  - A. Claims 1 – 4 are rejected under 35 USC § 102(b) as allegedly being anticipated by US Pat. No. 5,563,146 To Morris et al.
  - B. Claims 1 – 3 are rejected under 35 USC § 102(e) as allegedly being anticipated by US Pat No. 6,273,913 To Wright et al.
  - C. Claims 1 – 4 are rejected under 35 USC § 102(e) as allegedly being anticipated by US Pat No. 6,726,923 To Iyer et al.
- III. Claim 4 is rejected under 35 USC § 103(a) as allegedly being unpatentable over Wright et al., in view of Iyer et al.

### **I. The Claims Are Not Indefinite**

The Examiner states that several terms and/or phrases in either Claim 1 and/or Claim 4 result in either indefiniteness or ambiguity. For example, the Examiner alleges that: i) “generally” (*pg 6*); ii) “being selected from the group that includes” (*pg. 6*); iii) “any functional analog of sirolimus including” (*pg 7*); and iv) “... 32-dethoxy, 2-desmethyl and proline” (*pg 7*) are either indefinite or ambiguous. *Non-Final Office Action, 03/13/06*. The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 1 to delete the term “generally”. Further, a proper Markush Group is presented consisting of compounds that all comprise a rapamycin (i.e., sirolimus) structural core<sup>2</sup>. (See, Applicants' priority Patent 6,534,693, filed 01/31/01; col 4 ln 55-59; and Applicants' instant application pg 12 ln 12-18). Other amendments have been voluntarily made to

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<sup>1</sup> These arguments address rejections asserted in Office Action Mailed March 13, 2006.

<sup>2</sup> The Applicants believe that this Markush group is consistent with the “species election”.

Claim 1 intended to improve the overall clarity of the claimed embodiment. Concomitantly, the Applicants have also amended Claims 2 & 3, in order to maintain consistency with the above amendments to Claims 1 & 4. These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants respectfully request that the Examiner withdraw the rejection.

## **II. The Claims Are Not Anticipated**

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). This criterion is not met with any of the references cited by the Examiner.

### **A. Claims 1 – 4 Are Not Anticipated By Morris et al.**

The Examiner states that Morris et al. teaches a sheet of material by disclosing transdermal patches and stents:

Examiner views such delivery systems as transdermal patches or stent to fall within the instant limitation “material adapted for being wrapped generally around tissue of a human body” ...

*Office Action*, pg 9. The Applicants disagree. First, transdermal patches are not used for “placement onto a vessel”. Second, stents are taught for intravascular placement, and not extravascular placement.

With regard to the latter, the Examiner's view that stents are able to be “wrapped generally around tissue of the human body” is contrary to the actual teachings of Morris et al.:

Rapamycin ... can be administered intravascularly or via a vascular stent ... during balloon catheterization ...

*Morris et al. col 11 ln 29-33*. Clearly, Morris et al. contemplates that stents deliver rapamycin by insertion into a blood vessel and not “wrapped around” a body tissue. Further, the Examiner cannot make conclusory statements without finding explicit support in the cited reference.<sup>3</sup>

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<sup>3</sup> The Examiner is reminded that - under the law - an Examiner is NOT one skilled in the art; mere opinion of the Examiner on what one skilled in the art might believe does not count. *In re Rijckaert*, 9 F.3d 1531,

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 1 to recite "an annular surgical wrap" and added new dependent Claims 23 & 24 further defining this embodiment. *Applicants' Specification pg 10 ln 11-16, and Figures 7 & 8.* This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application. The Applicants believe this amendment is consistent with the Examiner's intended claim scope of Group I from the Restriction Requirement mailed Sept 22, 2005. The Applicants point out that original dependent Claim 6 has been mistakenly included in Group II (having a suture claim scope) and should have been included in Group I (having a surgical wrap claim scope)<sup>4</sup>. The Applicants respectfully request that the Examiner clarify the record.

The Examiner has not, and can not, point to any teaching in Morris et al. that teaches an annular surgical wrap having a centrally-located hole and a radial edge.

The Applicants respectfully request that the Examiner take note of new Claims 25-28 reciting a surgical wrap embodiment comprising oxidized regenerated cellulose. *Applicants' Specification pg 7 ln 29 – pg 8 ln 1.*

Consequently, Morris et al. does not teach all the claimed elements and cannot anticipate the Applicants' embodiment. The Applicants respectfully request that the Examiner withdraw the rejection.

**B. Claims 1 – 3 Are Not Anticipated By Wright et al.**

The Examiner states that Wright et al. teaches a sheet of material by disclosing polymeric sheets:

Wright specifically teaches polymeric sheets that can be wrapped around tissues of a human body ... Thus, Wright anticipates the limitations of the instant claims".

*Office Action, pg 9.* The Applicants disagree and point out that the Examiner's rejection is now moot due to the above described claim amendment. Further, the Examiner has not, and can not, point to any teaching in Wright et al. that teaches an annular surgical wrap having a centrally-located hole and a radial edge.

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28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art.").

<sup>4</sup> Independent Claim 5 does not recite "a suture".

Consequently, Wright et al. does not teach all the claimed elements and cannot anticipate the Applicants' embodiment. The Applicants respectfully request that the Examiner withdraw the rejection.

**C. Claims 1 – 4 Are Not Anticipated By Iyer et al.**

The Examiner states that Iyer et al. teaches:

... a drug-eluting biodegradable matrix comprising rapamycin for treating anastomosis. ... [and]... is capable of being wrapped around tissues of a human body ...

*Office Action pg 10 ¶ 18* [emphasis added]. Again, the Examiner makes the same mistake as with Morris et al. The Examiner is citing Iyer et al. as a reference for a method claim NOT a device and/or composition claim. Nonetheless, the Applicants point out that the Examiner's rejection is now moot due to the above described claim amendments. Further, the Examiner has not, and can not, point to any teaching in Iyer et al. that teaches an annular surgical wrap having a centrally-located hole and a radial edge.

Consequently, Iyer et al. does not teach all the claimed elements and cannot anticipate the Applicants' embodiment. The Applicants respectfully request that the Examiner withdraw the rejection.

**III. Claim 4 Is Not *Prima Facie* Obvious**

The Examiner states that Claim 4 is rejected under 35 USC 103(a) as allegedly being unpatentable under United States Patent No. 6,273,913 To Wright et al. in view of United States Patent No. 6,726,923 to Iyer et al. The Applicants disagree because the combined teachings of Wright et al. and Iyer et al. do not create a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. The Applicants submit that the Examiner's rejection does not

meet these criterion. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

**A. There Is No Motivation To Combine The Teachings Of Wright et al. And Iyer et al.**

On the one hand, the Examiner admits that:

Wright teaches local delivery of rapamycin from micropores in the body of a stent or a polymer coating applied on a stent.

*Office Action pg 9 ¶ 17.* On the other hand, the Examiner admits that:

Iyer describes a drug-eluting biodegradable matrix ... [that is] ... perivascularly wrapped around site of interest.

*Office Action pg 10 ¶ 18.* The Examiner has omitted an important aspect of the Wright et al. technology. The Applicants provide below the full context of Wright's Field Of Invention:

Delivery of rapamycin locally, particularly from an intravascular stent, directly from micropores in the stent body or mixed or bound to a polymer coating applied on stent ...

*Wright et al. col 1 ln 7-13* [emphasis added]. Wright et al. further describes the expansion of a stent "within the lumen of an angioplastied coronary artery". *col 4 ln 43-44.* Consequently, upon reading these teachings one having ordinary skill in the art would not be motivated to look to Iyer's perivascular wrap in order to improve Wright's intravascular coated stent technology.

Iyer et al. discusses the drawbacks of stent technology in relation to balloon angioplasty:

Stents are either "balloon-expandable" or "self-expanding" and when deployed endovascularly, abut against the inner vessel wall. Whether or not a stent is placed, this form of treatment has a high risk of failure ...

*Iyer et al. col 3 ln 1-4.* Clearly, upon reading these teachings one having ordinary skill in the art would not be motivated to look to Wright's intravascular stent technology in order to improve Iyer's perivascular wrap.

The Applicants argue that upon this basis alone, there is no *prima facie* case of obviousness and the Examiner is respectfully requested to withdraw the rejection.

**B. Wright et al. and Iyer et al. Do Not Teach All The Claim Limitations**

Even if Wright et al. and Iyer et al. were properly combined (which they are not) a *prima facie* case of obviousness would still fail. Even when improperly combined they fail to teach all the Applicants' claim limitations.

Neither reference discloses, teaches or suggests an annular surgical wrap comprising a centrally located hole, a radial edge and a drug related to rapamycin and an additional medication. First, the Examiner admits that:

Wright fails to explicitly combine another anti-inflammatory agent ...

*Office Action pg 11 ¶ 19.* On the other hand, Iyer et al. does not disclose any annular surgical wrap and therefore the recited elements within Claim 1 are imported into Claim 4. Consequently, Claim 4 is unaffected by Iyer et al.

**C. Wright et al. And Iyer et al. Provide No Expectation Of Success**

As pointed out above, neither Wright et al. nor Iyer et al. teach an annular surgical wrap. The Examiner is reminded that any reasonable expectation of success requires an explicit teaching within the cited reference:

The expectation of success must come from the prior art and explicitly predict that the process recited in the claims would work.

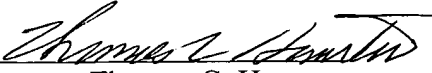
*In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988)[emphasis added]. The Applicants assert that the Examiner cannot point to to any teachings within Wright et al. or Iyer et al. that explicitly predicts a successful use of an annular surgical wrap.

Consequently, the Examiner's rejection fails and the Applicants respectfully request that the Examiner withdraw this rejection.

**CONCLUSION**

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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